

Remarks

Claims 11-30 were pending in the subject application. By this Amendment, claims 11, 12, 25, and 26 have been amended, claims 27-30 have been canceled, and new claims 31-34 have been added. Accordingly, claims 11-26, and 31-35 are currently before the Examiner. Favorable consideration and entry of the amendments presented herein are respectfully requested.

The amendments to the claims have been done to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments to the claims should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited. Support for these amendments and new claims can be found throughout the subject specification including, for example, at page 3, lines 5-13. The undersigned avers that no new matter is introduced by this amendment.

Claims 12-13, 15, 17, and 19 have been rejected under 35 U.S.C. §112, second paragraph as indefinite. Claim 12 has been amended to clarify that the plastic material is gas-impermeable and to provide consistency with dependent claims 15, 17, and 19. Further, the applicant respectfully submits that impermeability of the plastic material is consistent with a venting means in the enclosure as a whole. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Claims 25 and 26 have been rejected under 35 U.S.C. §112, second paragraph as indefinite. The applicant respectfully submits that the skilled artisan would readily understand the metes and bounds of the claims with respect to the terms "has a soft feel" in claim 25 and "at least partially transparent" in claim 26. However, in order to expedite prosecution, claim 25 has been amended to clarify that the plastic material is pliable and claim 26 has been amended to clarify visible accessibility to the wound. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph.

Claims 27-30 have been rejected under 35 U.S.C. §112, second paragraph as indefinite. In view of the cancellation of claims 27-30, the rejection of these claims is now moot. As noted above,

new claims 31-34 to more clearly recite a method that manipulates the structural limitations of the device. Accordingly, reconsideration and withdrawal of this rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 11, 21-22, and 25 have been rejected under 35 U.S.C. §102(b) as being anticipated by Andrews *et al.* (U.S. Patent No. 5,437,621). The applicant respectfully traverses this grounds for rejection because the Andrews *et al.* reference does not disclose a device that provides a moist and warm environment for the promotion of wound healing.

The device of the subject invention advantageously promotes healing of wounds by providing a warm and moist environment with adequate oxygenation and prevention of gross contamination. By maintaining such an environment, the subject invention allows natural exudates from the wound to carry material away from the affected site, thus encouraging wound healing. As discussed below, such a device is not taught or suggested by the cited references.

The Andrews *et al.* reference discloses a device that provides “a relatively dry surface...adjacent the injury” (col. 3, lines 60-61) using an inner layer “which enables moisture to be wicked away from the injury” (col. 3, line 40), a second absorbent layer (col. 3, lines 62-64), and a third gas-permeable layer (col.4, lines 3-7). The device according to the Andrews *et al.* reference prevents moisture from coming into contact with the injury. In contrast, the subject invention offers a device that provides “a warm and moist environment” for the wound (specification at page 3, line 32). By providing such an environment, the subject device advantageously promotes healing of the wound.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims,

determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey v. Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

As noted above, the Andrews *et al.* reference does not disclose a device that provides a warm and moist environment for the wound. Thus, under the applicable statutory and case law, the Andrews *et al.* reference does not anticipate the current applicant's claims. Therefore, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

Claims 12-13 and 15-18 have been rejected under 35 U.S.C. §103(a) as obvious over the Andrews *et al.* reference. The applicant respectfully traverses this grounds of rejection because the Andrews *et al.* reference does not teach or suggest the claimed device.

As acknowledged in the instant Office Action, the Andrews *et al.* reference does not teach the applicant's unique device. The device according to the Andrews *et al.* reference provides a dry environment by including two layers of absorbent material and a gas-permeable third layer (see for example, col. 6, lines 13-44). The Andrews *et al.* reference suggests a dry environment "can help prevent infection and promote healing" (see col. 6, lines 54-56). There is no reason to think that one skilled in the art would be motivated to modify the Andrews *et al.* device to incorporate a gas-impermeable plastic material. In fact, the emphasis on a dry environment essentially teaches away from the device of the current invention.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicant's disclosure that provides such a teaching, and the applicants' disclosure cannot be used to reconstruct the prior art for a rejection under §103.

This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Srock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art. . . .” *In re Dow Chemical Co.*, *supra* at 1531. (emphasis added)

The applicant respectfully submits that any suggestion to make a gas-impermeable enclosure could only be arrived at through hindsight reconstruction of the art which is improper. Rather, a person skilled in the art at the time of the subject invention, having knowledge of the Andrews *et al.* reference would have no reason to believe that, advantageously and unexpectedly, a moist and warm environment would promote wound healing. Accordingly, reconsideration and withdrawal of this rejection under 35 USC §103(a) is respectfully requested.

Claims 14, 19-20, and 27-30 have been rejected under 35 U.S.C. §103(a) as obvious over the Andrews *et al.* reference in view of the Weber *et al.* reference (U.S. patent No. 5,161,686). To the extent that this rejection might be applied to the claims now presented for examination, the applicant respectfully traverses this grounds of rejection because neither the Andrews *et al.* reference nor the Weber *et al.* reference, alone or in combination, teach or suggest the subject device or the claimed method.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine the teachings of the cited references to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). Mere identification in the prior art of various aspects of the technology, without any motivation, suggestion or teaching to combine the teachings to arrive at the claimed invention in its entirety, is insufficient to defeat patentability of the whole claimed invention. *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998). The applicant respectfully submits that the cited references are devoid of any teaching, suggestion, or motivation to combine them to arrive at the subject invention.

The applicant hereby incorporates and resubmits his remarks concerning the Andrews *et al.* reference as set forth in the preceding paragraphs to address this rejection. The Weber *et al.* reference teaches an odor-absorbing web material for use in medical material packages. The Weber *et al.* reference does not teach, either expressly or impliedly, a device that provides a warm and moist environment to promote the healing of a wound. Further, the Weber *et al.* reference fails to disclose a gas-impermeable enclosure for wounded limbs. Thus, the Weber *et al.* reference fails to remedy, or even address, the defects noted in the Andrews *et al.* reference. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

Claim 23 has been rejected under 35 U.S.C. §103(a) as obvious over the Andrews *et al.* reference in view of the Eischen, Sr. reference (U.S. Patent No. 5,868,690). The applicant respectfully traverses the rejection and submits that the Eischen, Sr. reference does not teach or suggest the subject invention.

In addressing this rejection, the applicant hereby incorporates and resubmits his remarks concerning the Andrews *et al.* reference as set forth in the preceding paragraphs. The Eischen, Sr. reference teaches a boot that incorporates an inflatable bladder to improve blood flow and provide appropriate pressure within the boot. The Eischen, Sr. reference fails to arrive at the applicant's device and fails to cure the defects noted above in the Andrews *et al.* reference. The Office Action provides no indication as to why the skilled artisan would have been motivated to combine, much less modify, the teachings of either the Andrews *et al.* or the Eischen, Sr. references to arrive at the

subject invention. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

Claim 24 has been rejected under 35 U.S.C. §103(a) as obvious over the Andrews *et al.* reference in view of the Augustine reference (U.S. Patent No. 5,947,914). The applicant respectfully traverses the rejection and submits that the Augustine reference does not teach or suggest the subject invention.

In addressing this rejection, the applicant hereby incorporates and resubmits his remarks concerning the Andrews *et al.* references as set forth in the preceding paragraphs. The Augustine reference discloses a wound covering with a reservoir to release medicaments. An important aspect of the subject invention is the gas impermeable enclosure that promotes healing by providing a warm and moist environment. This is not disclosed by the Augustine reference. Consequently, the skilled artisan would have had no reason to look to the Augustine reference for guidance in developing a gas-impermeable device for wounded limbs. Thus, the Augustine reference fails to remedy, or even address, the defects noted in the Andrews *et al.* reference. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and the amendment above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Marked-up Version of Substitute Claim Amendments

Marked-up Version of Substitute Claim AmendmentsClaim 11 (amended):

A device for protecting and promoting the healing of a wound on a limb wherein said device comprises an enclosure comprising a plastic material, wherein said enclosure has a closeable opening at an end thereof, a fastening means to enable the opening of said enclosure to be closed around the limb with [an affected part of the limb]the wound contained within said enclosure, and a fluid-absorbent material within said enclosure such that, when the device is applied to a limb with a wound, said fluid absorbent material is in contact with an unaffected part of the limb to prevent excoriation of the unaffected part of the limb; and wherein said device provides a warm and moist environment around the wound.

Claim 12 (amended):

The device according to claim 11, wherein said [enclosure]plastic material is gas-impermeable.

Claim 25 (amended):

The device according to claim 11, wherein said plastic material is pliable[ and has a soft feel].

Claim 26 (amended):

The device according to claim 11, wherein said plastic material is at least partially transparent to provide visible access to the wound.